



DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA-2013-0058]

Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs)

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This notice revises the Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs). The Model Specifications are guidelines for the performance and uniform testing of BAIIDs. These devices are designed to prevent a driver from starting a motor vehicle when the driver's breath alcohol concentration (BrAC) is at or above a set alcohol level. Every State in the United States has enacted a law providing for the use of BAIIDs as a sanction for drivers convicted of driving while intoxicated offenses. This notice revises the 1992 Model Specifications, to test BAIIDs for conformance. These Model Specifications are based, in part, on input from interested parties during an open comment period. This notice also indicates that NHTSA will delay rendering a decision about the feasibility and timing of a Conforming Products List (CPL) until more information is available. Accordingly, NHTSA plans to conduct an assessment to determine whether establishing and maintaining a CPL is feasible, prior to rendering a decision.

DATES: Effective Date: This notice is effective May 8, 2014.

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I. Background

In 1992, the National Highway Traffic Safety Administration (NHTSA) adopted and published Model Specifications for Breath Alcohol Ignition Interlock Devices (BAIIDs). (57 Fed. Reg. 11772.) Ignition interlocks are alcohol breath-testing devices installed in motor vehicles that require the driver to provide an acceptable breath sample

in order to start the engine. If the breath sample provided by the driver contains more than a predetermined alcohol concentration, the ignition interlock device prevents the vehicle from starting. Ignition interlocks also require drivers to provide breath samples periodically while the engine is running, to ensure that their alcohol concentration remain under the predetermined level.

Before NHTSA adopted the Model Specifications in 1992, a number of States enacted laws authorizing the use of “certified” BAIIDs. However, there was no single standard or test procedure among the States for certifying BAIIDs. Manufacturers of ignition interlock devices requested that the Federal Government develop and issue standards for certifying such devices rather than leaving the industry subject to numerous State standards and test requirements. After notice and comment, NHTSA adopted the Model Specifications for BAIIDs to provide a degree of consistency.

Since the Model Specifications were adopted in 1992, many States have incorporated them or some variation into their certification requirements. Persons required to use BAIIDs are generally under the direct supervision of a court or another State agency (e.g., Motor Vehicle Administration). All 50 States have enacted laws providing for the use of BAIIDs for impaired driving offenders. Currently, of these States, 18 mandate or highly incentivize the use of BAIIDs by all impaired driving offenders (including first-time offenders); an additional 20 States mandate the use of BAIIDs by repeat and/or high BAC offenders (at .15 or greater).

While many States have incorporated the Model Specifications to certify BAIIDs used by impaired driving offenders, there remains considerable variability among State certification requirements. Due to this variability and rapid technological advances in the

industry, States and manufacturers of BAIIDs had requested that NHTSA update the Model Specifications. They also urged NHTSA to test the devices against the Model Specifications and maintain a Conforming Products List (CPL) of devices found to meet the Model Specifications.

A. 2006 Request for Comments

In preparation for the revision of the Model Specifications, NHTSA published two notices in the Federal Register. On February 15, 2006 (71 Fed. Reg. 8047), NHTSA published a request for comments, explaining that the agency intended to revise the 1992 Model Specifications and was interested in obtaining comments from interested parties in 13 specific areas. The areas included: accuracy and precision requirements; sensor technology; sample size requirements; temperature extreme testing; radio frequency interference (RFI) or electromagnetic interference (EMI); circumvention testing; the vehicle-interlock interface; calibration stability; ready-to-use times; NHTSA testing; international harmonization; specifications for ignition interlock programs; and acceptance testing.

B. 2010 Proposed Model Specifications

In general, the comments to the 2006 notice were supportive of the agency's intent to revise the 1992 Model Specifications, but they noted that some adjustments were warranted to assure more consistency in the quality of equipment in use at that time. On October 6, 2010 (75 Fed. Reg. 61820), NHTSA published a separate notice containing proposed revisions to the 1992 Model Specifications. That notice addressed the 13 topics that had been listed in the Federal Register notice published in 2006. It also addressed additional issues that were raised in the comments responding to the 2006 notice, including:

set points; removable sensing heads or units; tampering testing; service interval; retests; among others.

II. Comments Received in Response to 2010 Notice

NHTSA received comments from 20 individuals and organizations in response to the 2010 notice, including five States (Iowa, Illinois, Oklahoma, Wisconsin and Colorado); nine BAIID manufacturers (Alcohol Countermeasure Systems (ACS), Alcohol Detection Systems (ADS), Consumer Safety Technology (CST), Draeger Safety Diagnostics, Guardian Interlock Systems, LifeSafer Interlock, National Interlock Systems, Omega Point Systems and Smart Start); one manufacturer of Evidential Breath Testing Devices (Intoximeters); one citizen; two coalitions/associations (American Association of Motor Vehicle Administrators (AAMVA) and the Coalition of Ignition Interlock Manufacturers (CIIM)); and two BAIID installers/providers (Ignition Interlock Systems of Iowa (IISI) and Road Safety Technologies).

A. General Comments

Many of the comments were supportive of the proposed changes to the Model Specifications. However, a number of comments raised serious concerns.

Many comments suggested that, despite NHTSA statements to the contrary, some aspects of the proposed Model Specifications seemed tantamount to program guidelines or design (and not performance) specifications. In addition, a number of comments suggested that NHTSA seemed “out of touch” with certain current State practices and technology, and the proposed Model Specifications seemed “inflexible” in some respects. These comments stressed that certain aspects of the proposed Model Specifications would

negatively impact technical innovation and State programs. Other, more technical, issues were also raised.

NHTSA appreciated receiving the many candid and thoughtful comments submitted in response to the 2010 notice. The agency has considered them carefully and made a number of revisions to the Model Specifications as a result. In particular, the agency agrees that the Model Specifications should define performance criteria and not specify design features. The agency also agrees that some decisions are programmatic in nature and should not be included in these Model Specifications, which are intended to apply to the performance of BAIID units, not the manner in which States and local jurisdictions conduct their programs. The agency defers to the discretion of States and local jurisdictions regarding programmatic decisions and, as appropriate, seeks to incorporate flexibility in these Model Specifications, in an effort to support the programmatic decisions of States and local jurisdictions.

In this notice, the agency first discusses these overarching issues, which generated the greatest number of comments. Discussions about the more technical issues, which relate more directly to particular sections of the Model Specifications, follow.

Another topic that generated many comments related to the question of whether NHTSA should undertake the responsibility of evaluating ignition interlocks against the Model Specifications and publish a CPL of devices meeting those specifications. For reasons described in more detail later in this notice (Section II.E.), NHTSA will delay rendering a decision about the feasibility and timing of a CPL until more information is available. NHTSA plans to conduct an assessment to determine whether establishing and maintaining a CPL is feasible, prior to rendering a decision.

B. Overarching Issues

1. Sensor Technology

The Federal Register notice published in 2006 indicated that the 1992 Model Specifications did not address the type of sensor technology that should be used to satisfy the performance requirements, and asked whether the Model Specifications should limit sensor technology to alcohol-specific sensors (such as fuel cell technology based on electrochemical oxidation of alcohol) or other emerging sensor technologies, or whether NHTSA should not specify the sensor technology and rely instead on performance requirements. (71 Fed. Reg. 8047.)

In the 2010 Federal Register notice, NHTSA stated that, while alcohol-specific sensor technologies have made great advances, the proposal would not limit the sensor technology used in the BAIIDs as long as the BAIID meets the performance requirements of the Model Specifications. In that notice, the agency expressed the belief that this approach would allow a wider variety of options, including the use of emerging technologies as they become available. (75 Fed. Reg. 61822.)

The agency received nine comments regarding this topic. The comments were overwhelmingly opposed to the agency's proposal not to specify or restrict sensor technology.

For example, Road Safety Technologies stated, "It is critical that the interlock device be as accurate as the technology can allow." (p. 1.) Similarly, LifeSafer asserted, "As jurisdictions have embraced and expanded their use of BAIID technology, they have demanded alcohol-specific sensor technology. [Interlocks that] are not alcohol-specific ... tarnish the reputation of the industry ..., [which] undermines interlock efficacy and

creates lasting misperceptions.” (p. 4-5.)_ AAMVA expressed its belief that “non-specific alcohol devices are prone to false positives and unwarranted lockouts, leading to a lower acceptance rate amongst drivers.” (p. 1.) Colorado stated, “it is unfortunate that the proposed specifications do not seize the opportunity to move all our programs towards greater success, customer convenience, acceptance and satisfaction by requiring alcohol-specific technology.” (p. 2.)

NHTSA agrees with the comments that the Model Specifications should ensure that BAIIDs are as accurate as possible and that it is not desirable to accept devices that generate high levels of false positives. The agency is also persuaded by the comments that current technology has progressed sufficiently to expect that BAIIDs should be able to distinguish between alcohol and other chemicals or substances. Accordingly, the Model Specifications provide in Test 12 and 13 that BAIIDs should distinguish between alcohol and other specific substances, such as acetone and cigarette smoke, which are commonly found on breath. BAIIDs that are unable to distinguish these substances from alcohol will not meet the Model Specifications.

Some comments went further and urged the agency to require fuel cell technology and/or ban the use of semi-conductors. NHTSA declines to take this further step, since requiring one particular technology or prohibiting another would be equivalent to setting a design (and not a performance) standard.

2. Removable Heads and Fixed Control Boxes

In the 2010 notice, NHTSA proposed that the sensing unit should not be removable because it can more easily be damaged or mishandled, leading to frequent repairs and increased cost. Accordingly, NHTSA proposed to test only BAIIDs without

removable sensing heads or units, though the agency clarified that it does not object to BAIIDs with a removable mouthpiece. (75 Fed. Reg. 61823.)

This aspect of the proposal generated a large number of comments in strong opposition. For example, Consumer Safety Technology (CST) stated that it found “the provision for the prohibition of removal of the sensing head to be inexplicable and unjustified.” (p. 1.) According to CST, “All ignition interlocks have removable handsets. This provision would make every interlock noncompliant.” (p. 1.) Road Safety Technologies pointed out that, “In practice, many interlock providers now recommend to their customers that the sensing head be taken inside to keep it warm or cool in inclement weather [or] to prevent the vehicle from being stolen.” (p. 1.)

Guardian asserted that placing a restriction on removable heads would be “design restrictive.” (p. 2.) Guardian continued, “There should not be any restriction of design imposed by NHTSA. If a BAIID can meet ... and successfully comply with the test requirements, the design of the device itself should be left to the manufacturer and the marketplace.” (p. 2.)

A number of State comments also opposed the restriction. According to Illinois, “Currently, [it] has seven vendors whose BAIIDs are certified by the Secretary of State, all of which use BAIIDs that have a removable sensing head ... The Illinois Secretary of State has administered a BAIID program since 1995 and not once during the past 15 years has the Secretary received any complaints from BAIID users, installers or vendors that the BAIID has been damaged or mishandled as a result of removal of the sensing head.” (p. 1) Objections were received also from other BAIID manufacturers, the Coalition of Ignition Interlock Manufacturers (CIIM), interlock providers, Iowa and

Oklahoma. Wisconsin did not oppose the restriction, but urged NHTSA to specify that the sensing head be removable only by the service provider; not the customer.

NHTSA has reconsidered this aspect of its proposal based on the comments. The agency acknowledges that prohibiting removable sensing heads may constitute a design (and not a performance) standard and may unintentionally stifle new technologies. In addition, it could interfere with current State practices. Accordingly, the revised Model Specifications do not state a preference with regard to whether BAIIDs should have removable sensing heads. However, a provision has been added to the General Provisions and Features section of the Model Specifications (Section C), providing that if the BAIID has a removable sensing head, the vehicle should not start without use of the sensing head.

To ensure performance, BAIIDs should be tested as a unit under appropriate tests, as provided in the Model Specifications, including Tests 5 and 6, under extreme temperature conditions. If a BAIID includes removable components, such components should be tested in accordance with the manufacturer's user instructions.

NHTSA has not adopted the recommendation from Wisconsin to specify that only service providers may remove the sensing heads. We believe that such a restriction is a programmatic decision and does not relate to the performance of BAIID units.

NHTSA also proposed that BAIID memory should be located in a fixed control box. This aspect of the proposal was intended to prevent damage to the BAIID memory.

Draeger agreed with this aspect of the proposal, stating that it will ensure data integrity. However, most comments opposed this part of the proposal. For example, National Interlock stated, "Current interlock technology stores data in the sampling head,

the control box or both. Regardless of the memory storage location, the data is preserved in memory for download ... We believe that it is not necessary for NHTSA to mandate that the memory storage be in a fixed control box.” (p. 2.) Similar comments were received from Smart Start. Guardian added that this proposed restriction would limit “innovation in product development and technological advancement” (p. 5.) and interfere with current State practices. Comments in opposition were received also from Iowa, Colorado, Ignition Interlock Systems of Iowa (IISI) and Alcohol Detection Systems (ADS). Oklahoma requested clarification of the terms “memory”, “fixed” and “control box.” (p. 2.)

NHTSA has carefully considered these comments. The agency wishes to ensure the integrity of the data. However, the agency does not wish to specify design features or unnecessarily stifle new technologies. It also does not wish to interfere with current State practices. Accordingly, the revised Model Specifications have been revised to remove the specification that the memory be contained in a fixed control box. The interlock data logger of each BAIID should be tested, wherever it is maintained under the manufacturer’s design.

3. *Retests*

As stated earlier, ignition interlocks test drivers for alcohol before they can start their vehicle’s engine. Interlocks also retest drivers for alcohol periodically while the engine is running. In the 2010 notice, the agency stated that “NHTSA does not intend that retests be conducted while the vehicle is moving, but rather while the engine is running with the vehicle stopped in a safe location on the side of the road.” (75 Fed. Reg. 61824.)

Many of the comments objected to this statement. For example, LifeSafer asserted, “All interlock vendors advise the client/user to pull off the road in a ‘safe’ place to take the retest. The practical reality is 99% of the 500,000-1,000,000 plus retests per day are not taken in this fashion, but rather safely delivered while the vehicle is in motion with little or minimal driver distraction.” (p. 3-4.) Some of the comments asked NHTSA for evidence demonstrating that drivers are at increased risk when taking a retest.

Colorado asserted that, while requiring that a retest be conducted while “stopped in a safe location . . . may appear to serve public safety, current interlock devices are designed to be so unobtrusive that they are easier to manipulate [than] a vehicle’s sound system, GPS or climate control system.” Moreover, Colorado argued that “there are too many traffic situations that make pulling over less safe, even with an extended period within which to deliver the sample” such as “long mountain tunnels” or “other congested environments with tight lanes and limited shoulders.” (p. 2.)

NHTSA is very concerned about distracted driving and the risks that distraction can pose for drivers and other road users. However, the agency acknowledges that it currently has little data regarding crashes involving drivers taking interlock retests. We will continue to monitor the data and respond to any new trends that are identified.

Draeger pointed out, in its comments, that the manner in which retests should be conducted “is a requirement for the driver and is not directly related to the BAIID itself or its design and functionality.” (p. 3.) NHTSA agrees with this assessment.

Accordingly, while the agency strongly urges drivers to conduct retests when and where it is safe to do so, the Model Specifications no longer specify how retests should be

conducted. This is more appropriately a function for States and local jurisdictions. The Model Specifications have been revised to remove this reference.

4. Alerts

In response to the 2006 notice, one commenter suggested that an interlock-specific tone (other than a honking horn) be used to alert outsiders to BAIID violations. In the 2010 notice, NHTSA responded that it does not believe that audible sounds or lights to alert the public to interlock violations are necessary. (75 Fed. Reg. 61826.) The agency did not include the suggestion in its proposal.

The comments in response to this aspect of the 2010 notice were mixed. Consumer Safety Technology (CST) agreed that “the honking of the vehicle horn is disruptive enough to attract attention to a driver in violation of a ... retest.” (p. 9.) Smart Start did not take a position about the horn, but expressed its belief that “it ... promotes unsafe driving when lights are flashing on and off to alert the public.” (p. 5.)

IISI requested the evidence that NHTSA relied on to reach the conclusion that audible sounds or lights are not necessary to alert the public to interlock violations. According to IISI, “Our technicians, who collectively meet with hundreds of IID users every day, would say that the threat of the honking horn on a failed or ignored random retest is the single greatest deterrent to the IID user’s attempting to have another person pass a test so the impaired driver can sneak home undetected.” (p. 1.)

Similarly, ACS asserted that NHTSA’s position “is contrary to 25 years of experience with alcohol interlock programs in which audible sounds and (to a lesser extent) visual indications are required by jurisdictional authorities as both a warning to others and a deterrent to the driver to ignore a retest requirement.” (p. 22.)

As stated above with regard to retests, NHTSA is concerned about distracted driving and believes that certain types of alerts may serve as a distraction to drivers. On the other hand, the agency acknowledges that alerts may play an important role in creating deterrence for drivers in violation of a retest, and in drawing the attention of other drivers on the offending motor vehicle.

More importantly, upon reconsideration, NHTSA has reached the conclusion that decisions about the types of alerts that may be required and/or permitted are programmatic in nature, and should be at the discretion of States and local jurisdictions. Accordingly, the Model Specifications do not address the use of alerts. Such decisions may vary from State to State, and the options that vendors choose to offer ultimately will be dictated through the marketplace.

5. Emergency Override

Some comments received in response to the 2006 notice stated that an emergency override is a useful feature. In the 2010 notice, NHTSA declined to propose that BAIIDs must include this feature (i.e., the ability to start the vehicle without a breath test) in order to meet the Model Specifications. However, should a BAIID be equipped with an emergency override feature, NHTSA proposed to test the feature, but indicated that it could start the vehicle only once. The 2010 proposal provided that whenever the override feature was activated, the BAIID must indicate the need for service and record the use of the emergency override. No additional emergency overrides should be allowed during the lifetime of the BAIID installation. The agency proposed to test this feature. NHTSA also proposed that this emergency override feature have a default to prevent an override from being used when the BAIID malfunctions or fails. (75 Fed. Reg. 61825-26.)

The comments received in response to this portion of the proposal were varied. CST argued that “emergency overrides should not be allowed as they essentially allow a drunk driver one free pass to drive drunk.” (p. 5.) ACS and LifeSafer both agreed that emergency overrides should be allowed, but disagreed that an override should be permitted only once during the lifetime of the installation. ACS pointed out that not all jurisdictions permit the use of an emergency override, but of those that do, “the restriction on use is typically once per monitoring period (service interval), rather than once per installation (program duration).” (p. 21.) LifeSafer also disagreed that the override feature should not function when the BAID malfunctions or fails. In fact, LifeSafer asserted, “From a service standpoint, this is exactly when an override should be allowed.” (p. 14.)

NHTSA believes the decision whether to permit the use of an emergency override feature is programmatic in nature and should be left to the discretion of States and local jurisdictions. Accordingly, as proposed, the Model Specifications do not address whether BAIDs should be equipped with an emergency override feature. The Model Specifications have been modified to remove specifications related to emergency overrides and they remove the proposed override test.

6. Calibration Stability and Service Interval

In the 2006 notice, NHTSA asked, “Is the duration of calibration stability testing sufficient? Should ignition interlocks be required to hold their calibration for a longer period of time, thereby requiring less frequent calibration checks?” (71 Fed. Reg. 8048.)

In the agency’s 2010 notice, in response to comments received, NHTSA explained that, “The 1992 Model Specifications called for calibration stability for 7 days

beyond the manufacturer's designated calibration stability period of 30, 45, or 60 days. For example, if the manufacturer required that the calibration of BAIIDs be checked after 60 days, the BAIID would need to hold the calibration for 67 days." (75 Fed. Reg. 61824.)

NHTSA proposed that BAIIDs "must hold calibration for a minimum 30 days plus the 7-day lockout countdown described previously (i.e., 37 days) in order to conform to the Model Specifications." NHTSA explained that, "Although some manufacturers have BAIIDs that are claimed to hold calibration for a longer time period, NHTSA proposes to test the calibration stability at 37 days (i.e., 30 days plus the 7-day lockout countdown)..." (75 Fed. Reg. 61824.)

NHTSA also proposed in the 2010 notice to add service interval requirements of "not greater than 30 days, plus a 7-day lockout countdown." (75 Fed. Reg. 61824.)

More than half of the comments addressed this issue. All of the comments objected to this aspect of the agency's proposal. Iowa described it as "a step backwards" (p. 1); Wisconsin said it is "overly restrictive" (p. 2); CST called it "an inexplicable regression in standards that will result in increased costs to the participant and consequently result in a marked reduction in participation in state interlock programs." (p. 3.)

CIIM explained that "This is an area where technology has significantly improved since the last time NHTSA asked for comments. Most devices can go 2 or 3 months without needing to have its calibration checked." (p. 2.) Accordingly, CIIM suggested a longer calibration period. ACS sought to clarify that calibration stability and service intervals are not the same. "Calibration stability is a performance criterion of the BAIID

to be included in Model Specifications; whereas, service interval is programmable as a function of the performance of a participant and is a program matter.” (p. 13.) In addition, National Interlock pointed out that, “The proposed [Model Specifications] would appear to prohibit specialized programming of the BAIID device or software to meet the specific requirements of jurisdictions.” (p. 2.)

NHTSA agrees with the comments that current technology now permits ignition interlocks to maintain stable calibration for longer periods of time. The Model Specifications continue to provide for a *minimum* calibration stability period of 37 days (30 days plus the 7-day lockout countdown) and for BAIIDs to be tested (under Test 3) to determine conformance with this period. This minimum calibration period should provide some consistency and the 30-day period would allow results of this test to be available quickly. In addition, in recognition of recent technological advances and current practice in the field, the Model Specifications provide manufacturers with the opportunity to demonstrate that their BAIIDs can maintain their calibration stability for longer periods of time, by providing for testing of BAIIDs also at 60 days, 90 days and 180 days, plus 7 days.

As suggested in the comments, NHTSA agrees that it is appropriate to decouple the period of calibration stability and the service interval. States and local jurisdictions make decisions about service intervals based on a number of different factors, including the need to supervise some offenders more closely or the desirability of providing an incentive (and permitting a longer service interval) for offenders who have demonstrated compliance with their sentence. In addition, NHTSA recognizes that BAIIDs can be programmed to vary the service interval, based on the circumstances in each case.

Accordingly, the Model Specifications do not provide for a specific service interval period. Rather, the agency defers to States and local jurisdictions to determine the service intervals they believe are appropriate.

However, in one important respect, these two periods are very much related. States and local jurisdictions are reminded that, if they choose to use service intervals that are longer than 37 days, the BAIIDs they select should be capable of maintaining a stable calibration for the requisite period of time.

Smart Start suggested that a maximum number of violation points should be defined and allowed, and recommended 5. (p. 4.) NHTSA believes that, like the service interval, this is a programmatic issue and should be set by States and local jurisdictions. Accordingly, the Model Specifications have not been modified to specify a maximum number of violation points.

C. Technical Issues Relating to Particular Sections of the Model Specifications

1. Terms Used in Model Specifications (Section B)

The 2010 notice contained proposed definitions for 14 terms. ACS took issue with the proposed definition for the term, “Service interval”, which the notice proposed to define as “The maximum time period that a BAIID may be used without maintenance or data download, after which the ignition must lock.” ACS pointed out that, “Service interval is not a device performance criteria; it is a program guideline, which is the time period during which the participant may drive between monitoring appointments, based upon the jurisdiction restrictions and the compliance of the participant with program

conditions.” (p. 26.) NHTSA agrees with this point and has changed the definition of this term accordingly.

Oklahoma suggested that the word “pertinent” should be removed from the proposed definition of “Interlock Data Logger – A device within a BAIID that records all pertinent events, dates and times during the period of installation and use of a BAIID.” NHTSA has made this modification, as well, to avoid limiting the information that is recorded on the interlock data logger.

Other comments supported the proposed definitions.

2. General Provisions and Features of BAIIDs (Section C)

The 2010 notice proposed that BAIIDs must meet certain requirements in order to conform to the Model Specifications, including:

- Pass conformance tests 1 through 16
- Not compromise normal functions of the vehicle
- Not have a removable sensing head
- Contain memory in a fixed control box
- Have tamper proof seals
- Capable of locking out a specified BrAC at a set point of .02 g/dL with a minimum flow rate of 0.1 L/sec
- Bypass or disable a remote start device, if installed on a vehicle
- Clear instructions to the driver
- An interlock data logger that will record all start attempts and outcomes
- Track all changes to the metrological software

In addition, the notice proposed that manufacturers of BAIIDs must submit:

- The operator’s manual and other documentation
- The quality assurance plan (QAP)
- A self-certification that the manufacturer meets the requirements of the U.S. Department of Health and Human Services, Public Health Service, Food and Drug Administration (FDA) Good Manufacturing Practices regulations for devices used for medical purposes (21 CFR Part 820) and that the device’s label meets the requirements contained in FDA’s Labeling regulations for devices used for medical purposes (21 CFR 809.10).

As discussed in detail previously, the agency received many comments concerning the removable sensing head and the fixed control box, and modifications have been made to the Model Specifications in response to these comments.

The comments concurred with most of the other requirements and features. However, comments were raised regarding some of these provisions.

a. Ignition, Ignition Switch and Locking - Oklahoma (p. 1) and ACS (e.g., p. 28-30) pointed out that the 2010 notice included some incorrect references to “ignition”, “ignition switch” and “locking” of the ignition. These references have been corrected.

b. Set point of 0.02 g/dL and minimum flow rate of 0.1 L/sec – In the 2006 notice, NHTSA asked whether the current set point of 0.025 grams of alcohol per 210 Liters of air (g/dL) is appropriate or whether it should be changed. (71 Fed. Reg. 8047.) The comments received in response to the 2006 notice were varied, including that the 0.025 g/dL level should not be changed, that the set point should be more stringent and

that the agency should establish a set point of 0.025 g/dL for adults and 0.02 g/dL for minors.

In response to these comments, in the 2010 notice, NHTSA proposed lowering the set point from 0.025 g/dL to 0.02 g/dL. (75 Fed. Reg. 61822.) Comments received in response to this aspect of the 2010 proposal were mixed again. For example, AAMVA questioned the need to lower the set point and suggested that a lower level could lead to unwarranted lockouts. (p. 2.) IISI asked whether this change was being proposed for the purpose of enforcing “abstinence from alcohol consumption” as opposed to ensuring “highway safety.” (p. 3.) Some comments, including those from Smart Start and Wisconsin, expressed support for the proposed change. LifeSafer supported the change and suggested that BAIIDs should be required to provide and record a “warn” when they register at 0.01 g/dL and above. (p. 5.)

The 2010 notice proposed a minimum flow rate of 0.1 Liters per second (L/sec). (75 Fed. Reg. 61823.) ACS suggested it should be set no lower than 0.2 L/sec. (p. 9.)

The agency is not attempting to influence program purposes, but rather is seeking simply to define the Model Specifications to test the precision and accuracy of BAIID devices. We recognize that State BrAC levels are not uniform. Most are set at 0.02 g/dL, but others are set at other (generally higher) levels. NHTSA continues to believe that 0.02 g/dL is an appropriate set point to use for the testing of BAIIDs under these Model Specifications. This set point will ensure accuracy for the States, whether they are using 0.02 g/dL or a higher level. That choice is still each State’s to make.

In addition, the change from 0.25 g/dL to 0.20 g/dL will align the BAIID Model Specifications with NHTSA’s other Model Specifications, which pertain to evidential

breath testing instruments (EBTs), calibrating units and alcohol screening devices.

Moreover, NHTSA continues to believe that the technology is available for BAIIDs to achieve and maintain a set point at this level. Accordingly, this portion of the proposed revision is adopted without change. The recommendation to require a “warning” at the 0.01 g/dL level has not been adopted, since practices vary from State to State.

NHTSA agrees with ACS’s comment regarding the flow rate. In fact, the 0.1 minimum flow rate included in the General Conditions and Features section of the notice was an unintentional error on the agency’s part. The General Test Conditions section of the 2010 notice stated that unless specified otherwise in a particular conformance test, each test would use an ambient flow rate of 0.3 L/sec. Consistent with this provision, the General Conditions and Features section should have indicated that BAIIDs be tested with a flow rate of 0.3 L/sec. The Model Specifications have been modified accordingly.

In accordance with the revised Model Specifications, BAIIDs should record and maintain a record of all breath samples provided.

c. Federal Drug Administration (FDA) Requirements- In the 2010 notice, in response to comments received regarding the 2006 notice, NHTSA proposed that manufacturers must submit a self-certification that the manufacturer meets the requirements of the FDA Good Manufacturing Practices (GMP) regulations for devices used for medical purposes (21 CFR Part 820) and that the device’s label meets the requirements contained in FDA’s Labeling regulations for devices used for medical purposes (21 CFR 809.10).

Some comments supported this aspect of the proposal. CST said that holding interlock providers to this “more rigorous” standard was “positive.” (p. 3.) ACS agreed,

in principle, with requiring that interlock manufacturers comply with FDA's GMP requirements, but asked how the requirement will be enforced? ACS did not believe a self-certification process would be adequate. (p. 24.)

However, most comments strongly objected to these requirements. The comments from National Interlock were representative. They stated, "The BAIID is not a medical device and is not intended to be used for medical purposes. The application of these regulations will place tremendous cost and burden on the manufacturers of BAIIDs, with the possibility of raising costs of programs beyond what is reasonable for a driver to pay. This could result in a higher incidence of individuals driving without a license, and without a BAIID, which would be contrary to federal and state policy to increase the use of BAIIDs as an alcohol countermeasure." (p. 2.) Draeger added, "Breath alcohol test systems intended solely for forensic (law enforcement) purposes are currently exempt from ... premarket notification and other FDA requirements... BAIID devices intended for use by law enforcement are therefore exempted by the FDA from GMP compliance... We recommend that NHTSA defer to the FDA's judgment and guidance on this matter..." (p. 4.)

It is NHTSA's understanding that the FDA Good Manufacturing Practices (GMP) regulations (21 CFR Part 820) apply to devices used for medical purposes. While the FDA has applied these regulations to some alcohol devices, such as screeners that are used for medical purposes, the FDA has not exercised jurisdiction over instruments used for other purposes, such as Evidential Breath Testing Instruments (EBTs), which are used for law enforcement purposes. Similarly, it is our understanding that, to date, the FDA has not exercised jurisdiction over BAIIDs. In addition, NHTSA has not, at this time,

reached a decision about whether it will develop a CPL. Accordingly, manufacturers of BAIIDs must comply with any applicable FDA requirements, but NHTSA has removed the reference in the Model Specifications to submission of a self-certification of compliance with the FDA regulations.

Smart Start (p. 6) and Guardian (p. 5) suggested that, if quality assurance requirements are to be imposed, NHTSA should consider using ISO standards instead of the FDA requirements. While manufacturers may adopt the ISO standards if they wish to do so, the agency does not believe there is sufficient justification to add this as a condition in the Model Specification for all manufacturers of BAIIDs.

3. BAIID Test Procedures (Section D)

The 2010 notice proposed to include 17 separate tests in the Model Specifications. It also proposed a number of general test conditions, pertaining to the number of trials, ambient temperature, ambient atmospheric pressure, sample parameters and simulated breath samples. In addition, the notice proposed a number of performance requirements relating to tests at 0.000 g/dL, 0.008 g/dL and 0.032 g/dL. The notice also proposed that a BAIID must be ready for use one minute after it is turned on and it must be ready for a second test within one minute of a preceding test.

a. General Test Conditions and Performance Requirements

The 2010 notice proposed that unless specified otherwise under a particular conformance test, BAIIDs must meet a number of performance conditions under all tests conducted.

i. Breath Sample Volume and Flow Rate

In the 2006 notice, NHTSA indicated that the 1992 Model Specifications set the minimum breath sampling size at 1.5 liters and asked whether NHTSA should consider lowering the minimum breath sampling size requirement. (71 Fed. Reg. 8047-48.) Most comments received in response to that notice advocated lowering the minimum sampling size to either 1.2 L or 1.0 L. In the 2010 notice, in response to these comments, NHTSA proposed lowering the minimum sampling size from 1.5 L to 1.2 L. Unless specified otherwise in the particular conformance test, BAIIDs should be tested at a volume of 1.2 liters and an ambient flow rate of 0.3L/sec. (75 Fed. Reg. 61822, 61828.) Breath sample volume relates to how much a person blows into a BAIID. Flow rate is the intensity of the blow.

The comments received in response to the 2010 notice were mixed. CST questioned the wisdom of lowering the minimum breath sampling size to 1.2 L, claiming that it could reduce the quality of the breath sample. (p. 3.) Wisconsin expressed a preference for retaining the size at 1.5 L (p. 2), as did Draeger, with allowances for reductions to 1.2 L upon medical recommendation (p. 4). On the other hand, Smart Start, ACS and LifeSafer all supported the reduction. Smart Start expressed the belief that this change would permit more individuals to participate in interlock programs. (p. 2.) ACS recommended that minimum back pressure also be included. (p. 8.)

NHTSA agrees that lowering the minimum breath sampling size will make the BAIID available to a larger population of users, including individuals with smaller or diminished lung capacity. No evidence was submitted to indicate that the reduced volume will diminish the integrity of breath samples. Accordingly, this element of the Model Specifications is adopted without change. If a State wishes to set its minimum

breath sampling size at 1.5 L and permit a 1.2 L level upon a medical recommendation, the Model Specifications will be able to support them in that decision. The ambient flow rate will remain at 0.3 L/sec. The agency believes that the other criteria included in the Model Specifications, provide sufficient safeguards against circumvention, without the need to address back pressure as well. Accordingly, a back pressure test has not been added.

ii. Precision

The 2010 notice stated that BAIIDs must experience no ignition locks in 20 trials at 0.000 g/dL (grams of alcohol/210 liters of air); not more than one ignition lock in 20 trials at 0.008 g/dL; and not more than one ignition unlock in 20 trials at 0.032 g/dL. (75 Fed. Reg. 61828.) These performance requirements represented an increase from 90 percent to 95 percent compliance at the 0.008 and 0.032 levels and 100 percent at 0.000.

Oklahoma suggested that no ignition “locks” should be permitted in 20 trials at both the 0.000 and 0.008 levels and no ignition “unlocks” should be permitted in 20 trials at the 0.032 level. (p. 3.) Wisconsin also recommended 100% conformance at all levels. (p. 2.) Smart Start asserted that the difference between 100% and 95% “does not matter.” Some changes in accuracy and precision “potentially [add] costs to the BAIID and [have] no real world added benefit.” (p. 1.) No other comments addressed this issue. In these revised Model Specifications, NHTSA has sought to strike a balance between the capabilities of the latest technology, the variability among various products currently on the market, as well as costs and other factors. Accordingly, as proposed in the 2010 notice, the performance requirements have been increased in these revised Model Specifications at the 0.000 level, by providing that the vehicle must not be prevented

from starting even once during 20 trials. However, the Model Specifications do not require 100 percent compliance at all levels. They provide that the vehicle must not be prevented from starting more than once during 20 trials at the 0.008 level and must not start more than once during 20 trials at the 0.032 level. (See Section D of the Model Specifications, Performance Requirements.)

iii. Terminology

ACS and Oklahoma noted that the terms “locked” and “unlocked”, while easily understood, are technically inaccurate. They suggest that they be replaced. The agency has made adjustments in these revised Model Specifications to avoid use of these terms, such as by describing whether or not the vehicle will start, instead of using the terms “locked” and “unlocked”.

iv. Readiness

The 1992 model specifications provided for a wait time of up to 5 minutes for a driver to take a breath test. A common complaint by users of BAIIDs was the long wait times for breath tests by BAIID users. Comments to the 2006 notice indicated that, with improved technology, faster ready-to-use times were achievable, even in extreme low temperatures because BAIIDs now have quick start capabilities.

The 2010 notice proposed that, unless specified otherwise in a particular test, BAIIDs must be ready for use within one minute after they are turned on and ready for a second test within one minute of a preceding test. (75 Fed. Reg. 61824.) A number of comments expressed concern that the proposed change was too extreme. ACS pointed out that, if the BrAC is at or above the set point, the BAIID will enter into a lock out period of 3-5 minutes. ACS stated, “The examiner must request special parameter

settings if a one minute retest period is required.” (p. 29.) LifeSafer made a similar comment, suggesting that 90 seconds should be allowed “to completely purge the prior alcohol-laden sample.” (p. 15.) NHTSA has decided to adopt a compromise readiness time period of 3 minutes as the performance level in the Model Specifications, which the agency believes is appropriate and achievable, based on current practices and the current state of technology. NHTSA has revised the Performance Requirements in Section D of the Model Specifications to provide for this change.

No other comments were received objecting to the General Test Conditions or Performance Requirements.

b. Conformance Tests

The 2010 notice proposed 17 separate conformance tests regarding the performance of BAIIDs. Some of the tests were supported by the comments. Questions, objections and suggestions were raised regarding others. Each test, the comments that it generated and the agency’s responses are discussed in detail below.

Test 1 – Precision and Accuracy

As explained in the 2010 notice, “accuracy” is the degree to which a BAIID measures the BrAC correctly. For example, for a BAIID to be accurate, a breath sample with no alcohol present (0.000 g/dL) must not prevent the vehicle from starting. “Precision” is the degree to which that same measure can be repeated. In the previous example, for the BAIID to be precise, that same alcohol free breath sample should not prevent the vehicle from starting consistently over time. (75 Fed. Reg. 61822.)

In the 2010 notice, NHTSA proposed testing BAIIDs at ± 0.012 g/dL above and below the set point of 0.02g/dL, i.e., at 0.032 g/dL and 0.008 g/dL. (75 Fed. Reg. 61822.)

Wisconsin suggested that testing should be carried out at ± 25 percent so that tests would be conducted at 0.015 g/dL rather than 0.008 g/dL and 0.025 g/dL rather than .032 g/dL. (p. 2.) All other comments either supported or did not object to the proposed levels. As explained in the 2010 notice, NHTSA arrived at these proposed levels by using standard statistical techniques for small samples. (75 Fed. Reg. 61822.) The ± 0.012 interval corresponds to a 2 sigma requirement for compliance. The levels proposed in the 2010 notice are adopted without change.

ACS suggested that the BAIID should record the measured BrAC value from the data log to conduct statistical analysis. (p. 29.) Draeger proposed adding a result requirement to each test point. (p. 4.) The Model Specifications do not require a numerical readout. They require only that the BAIID functions properly at each appropriate BrAC, by preventing or permitting a vehicle to start, as appropriate. BAIID manufacturers may offer a feature that provides a numerical readout, if they choose to do so. However, the Model Specifications do not specify that such a feature be offered and do not specify a test for that particular function.

Test 2 – Breath Sample Volume and Flow Rate

As described above, the General Test Conditions provide that, unless specified otherwise in a particular conformance test, all tests will be conducted using a volume of 1.2 liters and a flow rate of 0.3 L/sec. The purpose of Test 2 is to evaluate the performance of BAIIDs under different breath sample volumes and flow rates. Tests 2a and 2b are designed to test the amount (volume) of air blown into the BAIID, using a smaller and a larger sample volume (1.0 and 1.5 liters, respectively). Tests 2c and 2d are

designed to test the intensity (flow rate) of the blow, using a slower and a faster flow rate (0.1 and 0.7 L/sec, respectively).

The 2010 notice proposed that BAIIDs should prevent a vehicle from starting when the sample volume is 1.0 liters and permit the vehicle to start with a sample volume of 1.5 liters. (75 Fed. Reg. 61828.) These elements of Tests 2a and 2b are adopted without change.

The 2010 notice proposed that BAIIDs should permit the vehicle to start using both flow rates. (75 Fed. Reg. 61828.) As mentioned earlier in this notice in Section II.C.2.b., ACS commented that the flow rate should be set no lower than 0.2 L/sec (p. 9), and the agency agrees. Consistent with this change, the Model Specifications are revised to provide that BAIIDs should prevent a vehicle from starting when the flow rate is 0.1 L/sec and it should permit the vehicle to start with a flow rate of 0.7 L/sec.

Test 3 – Calibration Stability

These issues are discussed fully in Section II.B.6. above. In response to comments received, the Model Specifications continue to provide for a minimum calibration stability period of 37 days (30 days plus the 7-day lockout countdown) and BAIIDs should be tested (under Test 3) to determine conformance with this period. In addition, the Model Specifications provide manufacturers with the opportunity to demonstrate that their BAIIDs can maintain their calibration stability for longer periods of time, by providing for testing of BAIIDs also at 60 days, 90 days and 180 days, plus 7 days.

Test 4 – Input Power

No comments were received regarding this proposed test. It is adopted without change.

Tests 5 and 6 – Extreme Temperature and Humidity and

Warm Up Time at – 40° C

The 1992 Model Specifications called for testing at -40 °C, -20 °C, +70 °C and +85°C, but allowed for the removability of the alcohol sensing unit so that it may be kept at an artificial temperature when the vehicle may be subject to extremely cold or hot temperatures. In its 2006 notice, NHTSA asked whether this approach to extreme temperature testing seemed sufficient or whether it should be more stringent. (71 Fed. Reg. 8048.)

The agency received a variety of comments in response to the 2006 notice and, in 2010, proposed to retain the current extreme temperature tests at -40 °C and +85°C, believing it to be reasonably representative of the environments encountered in the United States. In addition, NHTSA proposed to conduct additional high temperature tests for components of the BAID installed in the passenger compartment (at +49°C) and in the engine compartment (at +85°C), and to specify the humidity level for these high temperature tests. The agency proposed to discontinue the tests at -20°C and +70°C, because the agency's experience indicated that testing at the extreme temperatures is sufficient. (75 Fed. Reg. 61823.)

NHTSA also proposed a warm up test in the 2010 notice to ensure that BAIDs are ready to test and ready for retest within 3 minutes under extreme temperature conditions, at -40 °C. (75 Fed. Reg. 61824.)

Draeger suggested that a warm-up time of up to 3 minutes at 9V and -40 °C is overly severe, and proposed that the test be changed to require a warm-up time of up to 3 minutes at 9V and -20 °C, but most comments supported the range that NHTSA proposed in the notice. (p. 5.)

Wisconsin applauded NHTSA's proposed adoption of tests at extreme temperatures, stating that "this will more effectively simulate BAIID operation in cold-weather climates. (p. 2.) ACS agreed that the proposed extreme temperature testing at -40 °C and +85°C should adequately address the needs of the environmental tests for the U.S. ACS disagreed that the -20°C and +70°C tests should be discontinued, asserting that these temperatures provide different stress levels on devices and that Tests 5 and 6 should be conducted under all of these conditions, and at +22°C, as well. (p. 9, 31.) Smart Start also suggested that the intermediate temperature tests should be retained. (p. 2.) LifeSafer urged the agency to harmonize the extreme temperature tests with the CENELEC (the European standard), at least on the high-side. (p. 7-8.)

NHTSA notes that the purpose of Tests 5 and 6 is to determine the BAIIDs' ability to perform at extreme temperatures and humidity. The temperatures that NHTSA included in the proposed Model Specifications are adopted without change, since they accurately represent extreme temperatures experienced in the United States. Other tests contained in the Model Specifications, including Tests 1-4 and others, should be performed at ambient temperatures. Accordingly, the agency believes intermediate temperatures need not be included under Tests 5 and 6.

Wisconsin recommended that the procedures used when testing at extreme temperatures must ensure that measurements are taken when the device is at the

prescribed temperature and humidity and has not been allowed to vary. (p. 3.) NHTSA agrees with this comment. Steps should be taken during testing to prevent temperature and humidity drift, such as by testing BAIID devices in a temperature chamber.

A number of comments objected specifically to the proposed requirements regarding readiness for retest at various temperatures. ACS asserted that the requirements are overly simplistic, requiring that BAIIDs are ready for retest within three minutes at -40 °C, and one minute at -39 °C. (p. 15.) Smart Start recommended that NHTSA consider adopting the CENELEC standard regarding this requirement, which provides that devices are to be tested at an ambient temperature of -40 °C and +85 °C with no time limit; at -20 °C within 3 minutes and at -5 °C within 90 seconds. (p. 4.)

Similarly, LifeSafer sought clarification regarding the readiness requirements for this test and others, noting that the various tests seem to require that devices need to be ready for retest within one minute, three minutes, five minutes or other periods of time. According to LifeSafer, retest sequences are typically 5-6 minutes before a Refused Violation is recorded. Imposing a 90 second wait between tests will allow a user three attempts to pass the retest. LifeSafer suggested that after a fail, a 90 second (versus a 60 second) interval between test attempts will produce a more precise result and is a reasonable period to require the user to wait after failing a test. (p. 11-12.)

NHTSA acknowledges that the variety of different wait times contained in the Model Specifications could cause confusion and has decided they are not warranted. Upon further review, the agency finds that it is preferable to establish more consistency in the readiness requirements and believes the objectives of each test can be achieved with a wait time of 3 minutes. Accordingly, NHTSA has revised the Model

Specifications to provide that BAIDs must be ready for all tests and retests within a period of 3 minutes. This change represents an improvement over the 1992 Model Specifications, is not as restrictive as the 2010 proposal and is consistent with (though not identical to) the European standard. See also the discussion above in Section II.C.3.a. of this notice.

Some comments addressed the voltage levels. Lifesafer, for example, expressed concern that the 9v level would be too low at -40 °C. (p. 15.) On the other hand, ACS agreed with the agency's proposal, stating that "this emulates a real world circumstance in a vehicle during winter months and with less than optimal batteries." (p. 10.) This was the agency's intention. NHTSA wanted to simulate less than optimal conditions, which commonly occur in winter. This aspect of the proposal is adopted without change.

Comments were received also concerning NHTSA's statements in the proposal prohibiting use of a removable sensing head. These comments are discussed in detail in Section II.B.2. above. As explained above, the revised Model Specifications do not prohibit the use of removable heads and provide allowances for these components under extreme temperatures, consistent with manufacturer instructions to users.

Test 7 – Vibration

The agency received no objections to the proposed vibration test, although ACS noted that, "Instead of interpreting the requirements of the vibration test," NHTSA could consider simply referring to "SAE standards for automobile electronic components." (p. 32.) This proposed test is adopted without change.

Test 8 – Retest

Under Test 8, NHTSA proposed a series of tests to simulate the BAIID functions that must operate in connection with retests once the vehicle has been started, including an indication to the driver that a retest must be taken, and an indication that a service call is required when tested with a BrAC of 0.032.

In the 2010 notice, the agency stated that it “does not intend that retests be conducted while the vehicle is moving, but rather while the engine is running with the vehicle stopped in a safe location on the side of the road.” (75 Fed. Reg. 61824.) This issue is discussed fully in Section II.B.3. above. In response to comments received, the preamble to this notice no longer specifies how retests should be conducted. The Model Specifications also are revised to remove this reference. They otherwise are not changed.

Test 9 – Tampering and Circumvention

In the 2006 notice, NHTSA stated that the 1992 Model Specifications offer a number of procedures for evaluating whether existing devices can be easily circumvented and it asked whether these procedures are sufficient or whether new or modified procedures should be added. (71 Fed. Reg. 8048.)

The comments to this notice criticized the Model Specifications for being confusing and lacking specificity. The comments offered a variety of specific suggestions. In the 2010 notice, NHTSA acknowledged that the circumvention requirements in the Model Specifications were confusing and proposed to clarify them and specify that BAIIDs must have tamper proof seals to indicate when a BAIID has been disconnected from the ignition. (75 Fed. Reg. 61823.) The 2010 proposal also included tests for “hot wiring”, push start, un-warmed air sample, warmed air sample, cooled 0.032 BrAC sample and filtered 0.032 BrAC sample. The proposal indicated that

each attempt must be noted on the interlock data logger. (75 Fed. Reg. 61829.) A sample format for downloaded data from an interlock data logger was included in Appendix D to the 2010 notice. (75 Fed. Reg. 61832-33.)

Smart Start supported the proposed tests, and emphasized the importance of anti-circumvention and anti-tampering techniques, stating, “There is a general mistrust in public perception that anyone can test on an interlock, thereby allowing the non sober driver to start their interlock equipped vehicle. NHTSA should take the lead in setting standards that negate this negative perception and instill public confidence in this technology that can separate drinking from driving.” (p. 3.)

However, Smart Start also suggested that the Model Specifications could go further. Other comments strongly agreed. Wisconsin stated, “Inclusion of tamper proof seals and routine monitoring for tampering during BAIID service does not go far enough to ensure that ignition interlock devices have sufficient features to prevent circumvention and the subsequent driving by impaired individuals. The proposed model specifications should require anti-circumvention measures in addition to electronically logging these events. These measures could include use of breath signature, humidity, differing blow patterns, photography, pressure, temperature or time to prevent BAIID circumvention.” (p. 4.)

The comments seem to support tests (a) and (b) (hot wiring and push start), but they criticized the other four tests. CST explained that these four tests “are based upon circumventions that plagued interlock programs in the early years of [such programs]. To even conduct these tests you would need an interlock with a very rare setting, the setting that allows the breath sample to be given in a long continuous blow.” (p. 4.)

Intoximeters asserted that tests (c) - (f) are intended to test the instruments' ability to prevent tampering and circumvention, "but in fact do not do so." According to Intoximeters, "Many BAIID devices are using a hum and blow or blow and hum method to determine if a person is providing the sample." (p. 1.) LifeSafer mentioned also other techniques, including the flow and suck back. (p. 9.) Intoximeters asserted, "It is disingenuous to show that an instrument is meeting these tests, when in fact the common anti-circumvention techniques are not being tested at all." (p. 1.) CST indicated that thirty eight states are already using these anti-circumvention breath sample patterns. (p. 4-5.) Intoximeter suggested that these anti-circumvention methods should be reviewed and tests should be established to determine if they can be beaten. (p. 1.)

Regarding Test 9b (push start), Draeger asserted that depending on the chosen technology, it may take up to 2 minutes until the movement or motor run is detected. Accordingly, Draeger suggested that the Model Specifications should be revised to provide that the vehicle be driven for at least two minutes. (p. 5.)

NHTSA has decided to continue to include the hot wiring and push start tests (9a and 9b) in the Model Specifications. To ensure that the results are properly recorded under the push start test, the Model Specifications specify that the vehicle should be run under this test for at least two minutes.

NHTSA recognizes that increasingly, interlock companies are introducing new, more sophisticated anti-circumvention features into their products, designed to ensure that the driver is blowing into the BAIID and to prevent circumvention. Manufacturers are employing a variety of anti-circumvention methods, including blow and hum, hum and blow, and suck and blow patterns, as well as the use of cameras. NHTSA appreciates

that these methods might make some of the tests proposed in the 2010 notice (9c – f) appear to be unnecessary or obsolete.

However, the revised Model Specifications do not specify the use of any particular type of anti-circumvention feature, since that would be tantamount to a design, rather than a performance, standard. In addition, since the technology associated with these features is still evolving and continuing to change rapidly, NHTSA will not attempt to establish further minimum performance criteria for this function at this time. Accordingly, at the present time, NHTSA will continue to include Tests 9c – f in the revised Model Specifications.

Test 10 – Restart of Stalled Motor Vehicle

Comments received in response to the 2006 notice suggested that restarts should be allowed only if a vehicle stalls, but not if the ignition is intentionally turned off or if a BAIID malfunctions or is awaiting a retest. In the 2010 notice, NHTSA proposed that a restart (i.e., without a breath sample) should be allowed when the vehicle stalls, provided the restart is accomplished in no more than 20 seconds. NHTSA also proposed that in all other situations where the vehicle malfunctions, the vehicle should be prevented from starting without a breath test. (75 Fed. Reg. 61825.)

The agency received a number of comments in response to this aspect of the proposal, all of which were in opposition. The comments uniformly argued that a period of 20 seconds is too short and could create unnecessary safety risks, particularly if a vehicle stalls in a hazardous area. Draeger pointed out that panic often occurs in a critical stall situation. (p. 5.) IISI asked whether NHTSA had received any reports that warranted a reduction in the “3 minute time period ... by nearly 90% to 20 seconds.” (p. 3.)

NHTSA acknowledges that stalls can take place in locations, such as on railroad tracks or in heavy traffic, which could present serious hazards should a driver be unable to restart the vehicle. While the comments suggested a variety of counter-proposals, ranging from 1 – 3 minutes, NHTSA notes that no comments, in response to either the agency’s 2006 notice or its 2010 notice objected to the 3 minute time period contained in the 1992 Model Specifications. Accordingly, the agency has decided to retain the time period of 3 minutes.

Test 11 – High Altitude

The 2010 notice proposed the addition of a high altitude test and proposed that it would apply only to BAIIDs using semiconductor alcohol sensors, based on a belief that high altitudes affect these types of sensors. (75 Fed. Reg. 61826, 61829.) Some comments objected to this unequal treatment. ACS did not object to inclusion of this test, but recommended that it be applied to all alcohol interlocks submitted for conformance testing. (p. 34.) CST asserted that this high altitude test is warranted also for fuel cell devices, but urged that “semiconductor technology should be outlawed” altogether. (p. 5.)

As explained earlier in this notice in Section II.B.1., the agency will not specify particular types of technology that should or should not be used. Instead, the Model Specification specify performance criteria to be met. To ensure consistent treatment of all instruments and to anticipate the possibility of other instruments that might be introduced into the marketplace, all BAIIDs should be tested under these high altitude conditions.

Test 12 – Cigarette Smoke

This proposed test would require a person who is alcohol-free to smoke approximately ½ of a cigarette, and wait one minute or a period specified by the BAIID manufacturer before testing. The proposal indicated that a simulator may be used in lieu of a smoker. (75 Fed. Reg. 61829.) ACS objected to this proposed test, stating “This is not a performance test equally applied to all BAIIDs if the manufacturer can specify how long to wait after the person smokes the cigarette.” ACS suggested instead that the test should specify, for example, that 30 seconds be applied equally to all BAIIDs. (p. 34.) NHTSA disagrees. Like some other elements of these Model Specifications, some conformance tests should be conducted in accordance with the manufacturer’s user instructions. If a manufacturer instructs users that they must wait 10 minutes after smoking a cigarette before they may use the BAIID, Test 12 should be conducted in accordance with those instructions. We note, however, that a BAIID that imposes this sort of limitation on the user may experience disadvantages in the marketplace. This aspect of Test 12 has been clarified, by specifying that the test should be conducted in accordance with the manufacturer’s user instructions.

ACS also asked about the possible use of a simulator to conduct this test. Specifically, ACS asked how the test would simulate a person who smokes ½ a cigarette and then wait a fixed period of time. (p. 34.) NHTSA no longer believes that a simulator needs to be used for the cigarette smoke test. Accordingly, reference to a simulator in this portion of the Model Specifications has been deleted. No other comments objected to this proposed test. It is otherwise adopted without change.

Test 13 – Acetone

The 2010 notice proposed adding an acetone test, based on NHTSA's belief that it is the most common interfering substance for BAIIDs. (75 Fed. Reg. 61826.) No comments objected to the inclusion of this test, although CST noted that "the concentration being used for the test is higher than would be experienced by a diabetic about to go into a diabetic coma, and thus ... does not really reflect real world conditions." (p. 5.) Wisconsin noted that alcohol-specific sensors, such as fuel cells, will have no difficulty passing this test, since substances other than alcohol will have no effect. However, Wisconsin urged that units that are not specific to alcohol, such as semi-conductors, "should be rigorously tested for the impact of interferences such as acetone and other volatile organic compounds." (p. 5.)

This test has been adopted with a lower concentration of acetone (115 microliters, rather than 230), which is a more realistic level. The test should be applied to all BAIIDs. No other changes have been made.

Test 14 – Emergency Override

This issue was discussed fully in Section II.B.5. NHTSA believes the decision whether to permit the use of an emergency override feature is programmatic in nature and should be left to the discretion of States and local jurisdictions. Accordingly, as proposed, the Model Specifications do not specify that BAIIDs be equipped with an emergency override feature in order to meet the Model Specifications. Since this feature is not specified, the Model Specifications will not include a test of this feature. The Model Specifications are modified to eliminate the reference to a feature that prevents an override from being used when the BAIID malfunctions or fails and it removes proposed Test 14.

Test 15 – Radiofrequency Interference/Electromagnetic Interference

In the 2006 notice, NHTSA explained that the RFI testing protocol in the 1992 Model Specifications uses power sources that are no longer commonly in use, but noted that new power sources that may interfere with the operation of BAIIDs (e.g., cell phones) have output power commensurate with equipment in use today. The agency asked what are the appropriate levels to measure RFI/EMI. (71 Fed. Reg. 8048.)

The comments pointed out that an increasing number of electronic devices are being operated in close proximity to BAIIDs, such as gaming, remote keyless entry, portable medical and Bluetooth-capable devices. The comments offered a variety of recommendations to address these potentially interfering power sources.

In the 2010 notice, NHTSA expressed its belief that the current specifications do not adequately define or describe RFI/EMI tests and proposed to test BAIIDs for emissions and transmissions of RFI/EMI and immunity to RFI/EMI using the SAE Surface Vehicle Standard J1113 series for Class C devices (devices essential to the operation or control of the vehicle) and the International Special Committee on Radio Interference (CISPR), Subcommittee of International Electro-technical Committee (IEC); specifically, CISPR 25, for RFI/EMI testing. NHTSA stated that it believed these procedures represent a broad consensus in the industry. (75 Fed. Reg. 61823.)

The agency received comments regarding this test from Smart Start, ACS, LifeSafer, ADS, CST and the State of Wisconsin. Most of the comments supported the proposed tests, although CST expressed the belief that the tests may be unnecessary. (p. 5.) ADS recommended that the appropriate level for testing should be 1W or less, since that level would be sufficient to identify potential cell phone interference. (p. 2.)

Wisconsin recommended that immunity testing for electrical equipment should be conducted in conformity with EN 61326-1:2001. (p. 5.)

The agency has not changed these elements of the Test. NHTSA believes the tests should not be limited to cell phone interference. The EN 61326-1:2001 test cited in Wisconsin's comment is used for remote locations, such as bridges, roads, etc., and not for motor vehicles.

Test 16 – Service Interval Display

As discussed more fully in Section II.B.6. and in the discussion regarding Test 3, NHTSA agrees that it is appropriate to decouple the period of calibration stability and the service interval. States and local jurisdictions make decisions about service intervals based on a number of different factors, including the need to supervise some offenders more closely or the desirability of providing an incentive (and permitting a longer service interval) for offenders who have demonstrated compliance with their sentence. In addition, NHTSA recognizes that BAIIDs can be programmed to vary the service interval, based on the circumstances in each case. Accordingly, the Model Specifications do not provide for a specific service interval period. Rather, the agency defers to States and local jurisdictions to determine the service intervals they believe are appropriate.

However, Test 16 has a different function. Its purpose is to ensure that the BAIID's display of the service interval is working properly. While NHTSA recognizes that service intervals may be set at a variety of time periods, the Model Specifications provide that a period of 30 days (with a 7-day lockout countdown) should be used for the purpose of this test. Under Test 16, after a period of 30 days, the BAIID should prominently display that the vehicle be taken to a designated maintenance facility for

maintenance and data downloads within seven days. This message should continue to be displayed for seven days. Following the seven-day period, if the BAIID is not serviced at a designated maintenance facility, it should not allow the vehicle to be started.

Test 17 – Data Integrity and Format

NHTSA proposed that the data be downloaded from the interlock data logger after all other tests have been completed. (75 Fed. Reg. 61831.) No comments objected to this requirement.

D. Other Comments Received Regarding the Model Specifications

1. Dust Test

In the 2010 notice, NHTSA indicated that one comment to the 2006 notice had suggested that several CENELEC standards be adopted into the Model Specifications, including the dust standard. The agency responded that in two decades of experience, NHTSA has received no reports suggesting that dust is an issue or source of concern in BAIIDs installed in vehicles. Accordingly, NHTSA did not propose to include a dust standard in the Model Specifications. (75 Fed. Reg. 61826.) A number of comments specifically agreed with the agency's decision, including Smart Start and IISI. A dust standard has not been added.

2. Vehicle-Interlock Interface

The 2006 notice indicated that anecdotal reports from ignition interlock manufacturers have suggested that it is sometimes difficult to install existing interlock systems in some of the newer electronic ignition systems. The agency asked whether NHTSA should establish any guidelines regarding the vehicle-interlock interface. (71 Fed. Reg. 8048.)

The comments received in response were mixed. In general, interlock manufacturers and providers supported a standard interlock-vehicle interface; vehicle manufacturers asserted that requiring a common interface presented significant challenges that could compromise vehicle ignition security systems and anti-theft immobilizing technologies. In the 2010 notice, NHTSA acknowledged that a common interface could afford installation convenience. However, the agency indicated that it would not specify such a requirement in the Model Specification and explained that “such a requirement goes beyond the scope of this proposal, which is limited to the BAIID itself and not to changes to the vehicle.” (75 Fed. Reg. 61823-24.)

The comments received in response to this issue were mixed. For example, National Interlock asked NHTSA to reconsider its decision and establish specifications regarding a common interface. (p. 1.) ADS said it would support this type of provision. (p. 2.) CST agreed with the vehicle manufacturers that a common interface could compromise anti-theft systems and should not be required. (p. 7.) Draeger expressed its view that requiring a specific interface on all vehicles might be impractical. (p. 3-4.) ACS agreed with the agency that the interface is beyond the scope of these Model Specifications. (p. 12.) CIIM argued that, “As advances in the automobile industry evolve, installation of interlock devices becomes more difficult. There are examples of installations taking hours, even days to complete as remote starters and push button ignitions become more prevalent.” CIIM urged NHTSA to “facilitate a dialogue between the two industries about this issue.” (p. 3.)

NHTSA will take CIIM’s recommendation under advisement. However, the agency continues to believe that a common interface in vehicles for ignition interlocks is

outside the scope of these Model Specifications. Accordingly, the agency has not included such a requirement in this notice.

3. International Harmonization

In the 2006 notice, NHTSA asked about the importance of harmonizing NHTSA's Model Specifications for BAIIDs with standards in other parts of the world. (71 Fed. Reg. 8048.) The comments received in response to this aspect of the notice were varied. Some comments supported harmonization with CENELEC (the European standard) due to increasingly global economy; others opposed harmonization based on a belief that aspects of the CENELEC standard are potentially restrictive and costly. In response, NHTSA proposed to maintain an independent set of Model Specifications, but to incorporate selected elements of the CENELEC, including vibration and cigarette smoke. (75 Fed. Reg. 61825.)

As noted above, the comments favored inclusion of these tests and some comments suggested that other CENELEC tests be included as well, including high temperature, dust and the drop test.

NHTSA has carefully considered other standards, including CENELEC, and as appropriate, has incorporated consistent provisions into these Model Specifications. In some cases, variations are warranted, based on cost, conditions and the manner in which BAIIDs are used in the United States. Further discussions regarding individual tests are contained in other sections of this notice.

4. Ignition Interlock Program Guidelines

In the 2006 notice, NHTSA asked whether the ignition interlock community (users, manufacturers, States, etc.) favor NHTSA development of an "interlock program"

in addition to Model Specifications for devices. (71 Fed. Reg. 8048.) Some comments supported the development of ignition interlock program guidelines; others expressed the belief that program guidelines have been and should remain a function of State government.

NHTSA did not include program guidelines in the 2010 notice, but indicated that the agency may explore the development of such guidelines in the future. (75 Fed. Reg. 61825.) The comments generally supported this position. AAMVA urged NHTSA to ensure that any such guidelines are “based on scientifically valid research” and “allow the necessary flexibility.” (p. 1.)

As stated earlier in this notice, NHTSA is committed to providing support, and not dictating practices, to the States. Over the last few years in particular, the agency has sought to provide information, support and technical assistance to the States in a variety of ways. NHTSA hosted a National Ignition Interlock Summit and invited representatives from every State to attend. NHTSA has also produced a number of publications containing information about ignition interlock programs, including “Ignition Interlocks – What You Need to Know: A Toolkit for Policymakers, Highway Safety Professionals and Advocates” (DOT HS 811 246), “Key Features for Ignition Interlock Programs” (DOT HS 811 262), National Ignition Interlock Summit Proceedings” (available on www.ghsa.org) and a series of New Mexico ignition interlock studies (see Traffic Tech 401; November 2010). In addition, NHTSA supported the development of the Alcohol Interlock Curriculum for Practitioners by the Traffic Injury Research Foundation (TIRF) (available on www.tirf.ca) and has supported technical assistance workshops, meetings and training (in cooperation with TIRF) and a series of

regional Ignition Interlock Summits (in cooperation with Mothers Against Drunk Driving). Also, NHTSA has provided financial assistance to support the establishment of a new National organization, representing State Ignition Interlock Program Administrators.

NHTSA will continue to provide support and assistance to States as they seek to expand and strengthen their ignition interlock programs, and the agency will consider whether the development of program guidelines would add value to the field. However, such guidelines are outside the scope of this notice and have not been included in the Model Specifications.

E. NHTSA Testing of BAIIDs and Conforming Products List (CPL)

In the 2006 notice, the agency asked, whether NHTSA should undertake the responsibility to evaluate ignition interlocks against its Model Specifications and publish a CPL of devices meeting those specifications. (71 Fed. Reg. 8048.)

In the 2010 notice, in response to comments received, NHTSA explained that the comments favored a certified testing laboratory program. Most advocated a NHTSA test program and the development of a CPL based on the Model Specifications. One commenter favored having a single private testing laboratory certified by NHTSA for this purpose. Several manufacturers noted significant problems with State certification requirements leading to questionable test results for some products. In general, both manufacturers and States favored a NHTSA test program because it would organize and standardize the industry and exclude less effective BAIIDs. One commenter suggested that NHTSA require BAIID re-certification in the event of an instrument design change and/or at some reasonable interval. (75 Fed. Reg. 61824.)

In the 2010 notice, NHTSA proposed to test BAIIDs for conformance with the Model Specifications. NHTSA also proposed to maintain and publish periodically a CPL with BAIIDs that have been tested and found to conform to the Model Specifications. NHTSA proposed to manage this new program as it does its other breath alcohol instrument testing programs. (75 Fed. Reg. 61824.)

NHTSA explained that testing of BAIIDs will be subject to the availability of Federal funds. If Federal funds are not available, NHTSA will discontinue testing BAIIDs until funds become available. (75 Fed. Reg. 61825.) In the proposed Submission Procedures contained in Appendix A of the 2010 notice, NHTSA proposed that it would “test BAIIDs on a first-come, first-served basis.” (75 Fed. Reg. 61831.)

More than half of the comments addressed this issue and many of them raised concerns, though the concerns expressed were varied. Some of the comments related to the potential of insufficient funds and whether Volpe has the capacity to conduct the testing. For example, Oklahoma stated, “We cannot support the limitation that ‘All tests are subject to the availability of Federal funds.’” (p. 2.) ACS asserted that “Volpe Laboratories lacks the equipment, expertise and perhaps financial resources to conduct the range of qualification tests on alcohol interlocks for conformance with the Model Specifications.” (p. 16.) The comments offered various possible solutions to address these concerns, including that the manufacturers fund the testing of BAIIDs (Smart Start), that there be a funding limitation (Draeger) or that NHTSA consider certifying independent laboratories to perform some or all of the testing (ACS, Alcohol Detection Systems, Draeger, Guardian, National Interlock, Coalition of Ignition Interlock Manufacturers).

In general, the comments were supportive of a NHTSA CPL. Guardian's comments were typical. They stated, "whether the test results are provided by NHTSA or by [an outside laboratory], a conforming product should be placed on the NHTSA conforming products list." Guardian asserted further, "If NHTSA cannot agree to this critical element, then there should NOT be a CPL for these products." (p. 2.)

While some comments seemed to express alarm about the statement in the 2010 notice that the testing program would be subject to the availability of funds, this limitation applies to all Federal programs, including NHTSA's current testing programs for evidential breath testers, calibrating units and other breath alcohol instruments and devices.

The Volpe National Systems Center is currently in the process of developing the capacity to conduct Radiofrequency Interference (RFI) and Electromagnetic Interference (EMI) testing. Volpe is capable of conducting all other tests delineated in the Model Specifications. NHTSA expects that Volpe will have the ability to conduct the RFI/EMI tests in the near future. Until then, Volpe has the ability to procure these tests from other qualified laboratories.

However, the comments raise a valid concern about the ability of any one laboratory, including Volpe, to test all available BAIID models in a sufficiently timely manner, especially during the initial period when these revised Model Specifications will initially go into effect. The agency also appreciates the concern that some comments expressed regarding the testing of BAIIDs on a first-come, first-served basis. The agency does not wish to take any steps that would create an unfair competitive advantage for some manufacturers over others.

Since these revised Model Specifications represent a substantial departure from the existing 1992 specifications, NHTSA will delay rendering a decision about the feasibility and timing of a CPL until more information is available about the implications for testing costs, resource requirements and the time necessary to conduct product testing.

Accordingly, NHTSA plans to conduct an assessment to determine whether establishing and maintaining a CPL is feasible, prior to rendering a decision.

If the agency determines that a CPL is feasible, NHTSA will announce its intention to develop a CPL in a Federal Register notice and will, at that time, outline the procedures that will apply, including steps for submitting BAIIDs for compliance testing. The agency would seek to establish procedures that ensure a level playing field, in terms of competition among ignition interlock manufacturers.

Accordingly, NHTSA expects that manufacturers will continue to certify, and States and local jurisdictions will continue to determine, that BAIIDs conform to the Model Specifications essentially in the same manner that is currently being used. However, the revised Model Specifications, rather than the 1992 version, should be used, once they become effective. The Model Specifications will not take effect immediately, but rather will be delayed for one year, to provide manufacturers of BAIIDs sufficient time to make conforming modifications to their instruments and to conduct testing, as warranted.

F. Appendices to the 2010 Notice

The 2010 notice contained four appendices. Appendix A included submission procedures for conformance testing of BAIIDs. (75 Fed. Reg. 61831.) Appendix B included procedures for the re-examination of BAIIDs, which occur at the sole discretion

of NHTSA. (75 Fed. Reg. 61831-32.) Appendix C provided a template for a Quality Assurance Plan. (75 Fed. Reg. 61832.) Appendix D provided a sample format for downloaded data from the interlock data logger. (75 Fed. Reg. 61832-33.)

As explained above, NHTSA has not yet decided whether it will develop a CPL. It will first conduct an assessment to determine its feasibility. If the agency decides that a CPL is feasible, NHTSA will publish a Federal Register notice announcing its plans to proceed and will, at that time, outline the procedures that will apply.

Accordingly, the first two appendices that were contained in the 2010 notice (then identified as Appendix A and Appendix B) are not included in this notice. The other two appendices that were contained in the 2010 notice (then identified as Appendix C and Appendix D) have been renamed as Appendix A and Appendix B, respectively.

III. New Model Specifications

On October 6, 2010, NHTSA proposed revisions to the 1992 Model Specifications for BAIDs. (75 F. R. 61820.) Those proposed revisions were based, in part, on input from the comments received in 2006. Today, in response to the October 6, 2010 notice, the 1992 Model Specifications have been revised.

This Notice is not intended to take the place of any State certification requirements; rather, it provides for a voluntary testing and conformance program.

These Model Specifications do not have the force of regulations and are not binding. States and others may adopt these Model Specifications and rely on any tests that NHTSA may conduct, or they may conduct their own tests according to their own procedures and specifications.

After consideration of the comments, the Model Specifications for Breath Alcohol Ignition Interlock Devices have been revised to reflect the decisions discussed above and are set forth below.

(Authority: 23 U.S.C. 403; 49 CFR 1.95; 49 CFR Part 501)

MODEL SPECIFICATIONS FOR

BREATH ALCOHOL IGNITION INTERLOCK DEVICES (BAIIDs)

A. Purpose and Scope

The purpose of these specifications is to establish recommended performance criteria and test methods for breath alcohol ignition interlock devices (BAIIDs), commonly referred to as alcohol interlocks or ignition interlocks. BAIIDs are breath alcohol sensing instruments designed to prevent the motor vehicle from starting unless the driver first provides a breath sample whose alcohol concentration is below the set point into the BAIID. If the measured breath alcohol concentration (BrAC) is at or above a set level, the vehicle will not start. BAIIDs are currently being used as court sanctions as well as administrative conditions of licensure. Drivers convicted of impaired driving may be required to use BAIIDs in their vehicle under court supervision or as part of a required path to full reinstatement of driving privileges. These specifications are intended for use in conformance testing of BAIIDs installed in vehicles. These specifications are voluntary and do not impose any compliance obligations on BAIID manufacturers or others.

B. Terms

Alcohol – Ethanol or ethyl alcohol (C₂H₅OH).

Alcohol set point – Breath Alcohol Concentration (BrAC) at which a BAIID is set to prevent a vehicle from starting.

Breath Alcohol Concentration (BrAC) – The amount of alcohol in a given amount of breath, expressed in weight per volume (w/v) based upon grams of alcohol per 210 liters (L) of breath, in accordance with the Uniform Vehicle Code, Chapter 11, Section 11-903.4 and 5.¹

Breath alcohol ignition interlock device (BAIID) – A device that is designed to allow a driver to start a vehicle if the driver's BrAC is below the set point and to prevent the driver from starting the vehicle if the driver's BrAC is at or above the set point.

Breath Sample – Normal expired human breath primarily containing air from the deep lung.

Calibration Stability – The ability of a BAIID to hold its accuracy and precision over a defined time period.

Circumvention – An attempt to bypass the correct operation of a BAIID, whether by use of an altered breath sample, by starting the vehicle by any means without first providing a breath sample.

Filtered air sample – Any human breath sample that has intentionally been altered so as to remove alcohol from it.

Interlock Data Logger – A device within a BAIID that records all events, dates, and times during the period of installation and use of a BAIID.

Retest – A breath test that is required after the initial engine start-up breath test and while the engine is running. This is also referred to as a running retest.

¹ Available from the National Committee on Uniform Traffic Laws and Ordinances, 107 South West Street, #110, Alexandria, VA 22314 (<http://www.ncutlo.org>).

Service Interval – The time period established by the State or jurisdiction that a BAIID may be used without maintenance or data download. If the device is not serviced within the period, warnings are provided and the device will prevent further operation.

Simulator – A device that produces an alcohol-in-air test sample of known concentration (e.g., a Breath Alcohol Sampling Simulator (BASS))² or a device that meets the NHTSA Model Specifications for Calibrating Units (72 FR 34742)).

Tampering – An attempt to physically disable, disconnect, adjust, or otherwise alter the proper operation of a BAIID.

C. General Provisions and Features of BAIIDs

Conforming BAIIDs must meet the following provisions:

The BAIID must pass each of the conformance tests 1 through 16 in Section D, unless explicitly excluded from a test by the specific terms of these specifications.

Installation and service of the BAIID in a vehicle must not compromise any normal function of the vehicle, including anti-theft functions, on-board computer functions, or vehicle safety features required by the Federal Motor Vehicle Safety Standards, and must not cause harm to the vehicle occupants. Care should be taken to protect against reverse polarity and damage to other circuits and to ensure that the BAIID does not drain the vehicle's battery while in sleep mode (i.e., power save mode).

The BAIID must have tamper proof seals to indicate when a BAIID has been disconnected from the ignition.

The BAIID must be capable of permitting a vehicle to start or preventing it from starting at specified breath alcohol concentrations.

² See NBS Special Publication 480-41, July 1981. Available from Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

The BAIID must be tested at an alcohol set point of 0.02 g/dL with a flow rate of 0.3 L/sec. Upon detecting an alcohol concentration at or above that set point, the BAIID must prevent the vehicle from starting for a period of time before another test can be performed.

If the vehicle is equipped with a remote start device, the BAIID must be installed so that the remote start function is bypassed or disabled and a valid breath test must be performed before the vehicle may be started.

If the BAIID has a removable sensing head, the BAIID may not allow the vehicle to start without use of the sensing head.

The BAIID must include clear instructions to the driver (e.g., when to blow, when to wait, when to start the vehicle, when to retest, when a lockout countdown occurs, including the time remaining before the BAIID may be used again to start the vehicle, and when to seek service).

Manufacturers must submit the operator's manual (user's guide or instructions to the user), the maintenance manual, and specifications and drawings fully describing the BAIID.

In addition, manufacturers must submit the quality assurance plan (QAP). The QAP must include the following information: instructions for checking the calibration of the BAIID (i.e., recommended calibrating unit, BrAC of 0.02 g/dL, agreement not greater than ± 0.005 BrAC, verification of accuracy of readout, actions to take for failed calibration check), instructions for downloading the data from the interlock data logger, instructions to maintain the BAIID, instructions on checking for tampering, and any other

information regarding quality assurance unique to the BAIID. See Appendix A for a sample QAP template.

The design of the BAIID must include an interlock data logger that will record, at a minimum, all start attempts and outcomes, including an emergency override if applicable, delineation of calibration checks, circumvention, tampering, operator attempts to start the vehicle, and BrAC for each start attempt. The data must be presented in chronological order (i.e., by date and time of event). See Appendix B for a sample format for downloaded data from the interlock data logger. The manufacturer must provide a means of downloading the data from the interlock data logger.

Any change to a BAIID that could affect its performance, including potentially software changes, should require additional testing. The BAIID must track all changes to the metrological software and indicate the software version and date on all printed and downloaded reports. NHTSA is aware that States (and local jurisdictions) use different set points in their interlock programs, and changes to the set point, alone, would not require additional testing. The Model Specifications provide that BAIIDs are to be tested at an alcohol set point of 0.02 g/dL.

D. BAIID Test Procedures

General Test Conditions

Unless otherwise specified in a conformance test, the following conditions apply to each test:

- Number of trials at each alcohol level = 20
- Ambient temperature: $22\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$ ($71.6\text{ }^{\circ}\text{F} \pm 5.4\text{ }^{\circ}\text{F}$).
- Ambient atmospheric pressure: $97.5\text{ kPa} \pm 10.5\text{ kPa}$ (25.7 and 31.9 inches Hg).

- Sample parameters: volume 1.2 liters; ambient flow rate 0.3 Liters per second; maximum delivery pressure 2.5 kPa; temperature 34 °C (93.2 °F)
- Simulated breath samples will be generated by the BASS³ or by a wet bath type calibrating unit that is listed on the NHTSA Conforming Products List for such devices. Solutions used in the calibrating device will be prepared as described in the NHTSA Model Specifications for Calibrating Units published June 25, 2007 (72 FR 34742).

Performance Requirements

Unless otherwise specified in a conformance test, the BAIID must meet the following performance requirements in each test:

- Tests at 0.000 g/dL BrAC: the vehicle must not be prevented from starting during 20 trials.
- Test at 0.008 g/dL BrAC: the vehicle must not be prevented from starting more than once during 20 trials.
- Tests at 0.032 g/dL BrAC (grams alcohol/210 liters of air): the vehicle must not start more than once during 20 trials.
- A BAIID must be ready for use 3 minutes or less after it is turned on. A BAIID must be ready for a second test within 3 minutes or less of a preceding test.

Conformance Tests

Unless otherwise specified in a test, these conformance tests need not be conducted in any particular order. Except when a test or portion of a test specifically requires the use

³ See NBS Special Publication 480-41, July 1981. Available from Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

of a motor vehicle, either a motor vehicle or a bench test set-up that simulates the relevant functions of a motor vehicle may be used.

Test 1. Precision and Accuracy

Test the BAIID at the following alcohol concentrations:

- a. 0.000 g/dL BrAC,
- b. 0.008 g/dL BrAC, and
- c. 0.032 g/dL BrAC.

Test 2. Breath Sample Volume and Flow Rate

Use a mass flow meter to monitor sample volume. Conduct each test (a - d) five times.

- a. Test at 0.000 g/dL BrAC with sample volume 1.0 liter. The BAIID must prevent the vehicle from starting and indicate insufficient volume 5 out of 5 times.
- b. Test at 0.000 g/dL BrAC with sample volume 1.5 liters. The BAIID must permit the vehicle to start 5 out of 5 times.
- c. Test at 0.000 g/dL BrAC with sample volume 1.2 liters at 0.1 L/s. The BAIID must prevent the vehicle from starting 5 out of 5 times.
- d. Test at 0.000 g/dL BrAC with sample volume 1.2 liters at 0.7 L/s. The BAIID must permit the vehicle to start 5 out of 5 times.

Test 3. Calibration Stability

Initialize the BAIID to begin the calibration stability test. A BAIID must not be re-calibrated after the start of Test 3. Conduct Test 1. Repeat Test 1 at 37 days. Test 2 and Tests 4 – 15 may be performed between these two Precision and Accuracy tests.

If requested by the manufacturer, repeat Test 1 at 67 days, 97 days and 187 days. These additional tests are optional. They exceed the minimum requirements of this test.

Test 4. Input Power

Conduct Test 1b and Test 1c at the following input power conditions:

- a. Test at 11 VDC input power.
- b. Test at 16 VDC input power.

Test 5. Extreme Temperature and Humidity

Using a temperature/humidity chamber:

- a. Soak the BAIID at -40 °C (-40 °F) for 1 hour, then conduct Test 1b and Test 1c at that temperature using 9 VDC input power.
- b. Soak the BAIID at 49 °C (120 °F), 95 percent relative humidity for 1 hour, then conduct Test 1b and Test 1c at that temperature and humidity using 16 VDC input power.
- c. This part of the test applies only to BAIIDs with components installed in the engine compartment. Soak the components of the BAIID that are installed in the engine compartment at 85 °C (185 °F), 95 percent relative humidity for 1 hour, then conduct Test 1b and Test 1c at that temperature and humidity using 16 VDC input power. The components that are installed in the passenger compartment should remain at ambient temperature and humidity conditions. Removable components will be tested in accordance with the manufacturer's instructions to the user. (See General Test Conditions).

Test 6. Warm Up Time at -40 °C

Using a temperature chamber, soak the BAIID for 1 hour at -40 °C. With input power set at 9 VDC, the BAIID must be ready to test in 3 minutes, and ready to retest in 3 minutes after being turned on. Conduct Test 6 five times. The BAIID must indicate that it is

ready to test or ready to retest in 3 minutes all five times. This test may be conducted in conjunction with Test 5 Extreme Temperature and Humidity.

Test 7. Vibration

Vibrate the BAIID in simple harmonic motion on each of three main axes uniformly through the frequency schedule specified below. For components not intended to be mounted on the engine, vibrate according to Test 7a; for components intended to be mounted on the engine, vibrate according to Test 7b. If a BAIID consists of several components connected by electrical wires or connected wirelessly, vibrate these components separately. After completion of the vibration, remove the BAIID from the shake table and conduct Test 1b and Test 1c.

Vibration Frequency Schedule

Test 7	Frequency range, Hz	Number of cycles	Sweep rate, octave/min	Amplitude, inches 0 to peak	Acceleration, gravity (g), 0 to peak
a	10 to 500	10	1	0.2	3
b	10 to 500	10	1	0.08	15

Test 8. Retest

If a BAIID includes a feature designed to detect whether the vehicle is moving, conduct Test 8 using a motor vehicle. If a BAIID does not include a feature designed to detect whether the vehicle is moving, conduct Test 8 using a motor vehicle or a bench test set-up that simulates the relevant functions of a motor vehicle.

- a. Within an interval of 5 to 7 minutes after a vehicle successfully starts, using a 0.000 g/dL BrAC test sample, and while the engine is still running, the BAIID must indicate that a second breath sample is required. Conduct Test 1b five times. The BAIID must treat this test as a passed retest all 5 times.

- b. Within an interval of 5 to 7 minutes after a vehicle successfully starts, using a 0.000 g/dL BrAC test sample, and while the engine is still running, the BAIID must indicate that a second breath sample is required. Conduct Test 1c five times. The BAIID must treat this test as a failed retest and prominently indicate the need for a service call.

A failed retest must be identified as an alert condition and flagged on the interlock data logger. A missed retest must be flagged on the interlock data logger. After the driver is alerted to retest, if the engine is accidentally or intentionally powered off, the BAIID must not allow the vehicle to start without a service call.

Test 9. Tampering and Circumvention

Attempt to start the ignition as indicated below. Conduct each test (a through f) five times. Each attempt to start the engine must be logged by the interlock data logger.

- a. “Hot wiring”. Start the engine by electrically bypassing the BAIID. The interlock data logger must record the ignition on with no breath test.
- b. Push start. A motor vehicle must be used for this part of Test 9. Use a vehicle equipped with a manual transmission. Start the engine by pushing the vehicle with another vehicle or by coasting the vehicle downhill before engaging the clutch. The vehicle must run for at least two minutes. The interlock data logger must record the ignition on with no breath test.
- c. Un-warmed air sample. Deliver an alcohol-free air sample of at least 2 liters into the BAIID using an air filled plastic bag which is fitted to the sampling tube and squeezed in a manner that mimics a person blowing into the BAIID. The vehicle must not start.

- d. Warmed air sample. Prepare a 12-ounce foam coffee cup fitted with a bubble tube inlet and a vent tube (rubber or tygon tubing) attached through the plastic lid. Fill the cup with 8 ounces of water warmed to 36 °C and attach the lid. Attach the vent tube to the BAIID and pass an air sample of at least 2 liters through the bubble tube into the heated water and thence into the BAIID. The flow rate must not be high enough to cause a mechanical transfer of water to the BAIID. The vehicle must not start.
- e. Cooled 0.032 BrAC sample. Attach a 4 foot long tygon tube of 3/8 inch inside diameter which has been cooled to ice temperature to the inlet of the BAIID, then test at 0.032 BrAC. The vehicle must not start.
- f. Filtered 0.032 BrAC sample. Prepare a 1 to 2 inch diameter 3 to 5 inches long paper tube loosely packed with an active absorbent material. Use loose cotton plugs to retain the absorbent in the paper tube. Pack the tube so that a person can easily blow 2 liters of air through the assembly within 5 seconds. Test the absorbent by passing a 2 liter 0.032 BrAC sample through the assembly within 5 seconds. If the air passing out of the BAIID is found to have a concentration of 0.006 BrAC or less, prepare 5 tubes packed in the same manner, fit separately to the BAIID and test at 0.032 BrAC. The vehicle must not start.
- g. Alternative to Tests 9c - 9f. If a BAIID includes an anti-circumvention feature designed to ensure that the driver is blowing into the BAIID, test its operation at 0.000 BrAC in lieu of tests 9c – 9f.

Test 10. Restart of Stalled Motor Vehicle

Conduct Test 10 using a motor vehicle.

Using a 0.000 g/dL BrAC sample, turn on the ignition. Turn off the ignition. Attempt to restart the ignition without a breath sample in less than 3 minutes – the vehicle must start. Turn off the ignition. Attempt to restart the ignition without a breath sample within 3 minutes after turning off the ignition – the vehicle must not start. Conduct Test 10 five times.

Test 11. High Altitude

Conduct Test 1b and Test 1c each at pressures of 80 kPa and 110 kPa (600 mmHg and 820 mmHg). Conduct Test 11 five times at each indicated pressure. At indicated pressure levels, for Test 1b, the ignition must treat the test as a passed test; for Test 1c, the ignition must treat the test as a failed test.

Test 12. Cigarette Smoke

Direct a cigarette smoker, who is alcohol-free, to smoke approximately ½ of a cigarette. The smoker must wait 1 minute or the period specified by the BAIID manufacturer in its user instructions before testing. Conduct Test 12 three times. The vehicle must start.

Test 13. Acetone

Test the BAIID for acetone interference. Conduct Test 1b by adding 115 microliters of acetone⁴ to the 500 milliliters of .008 g/dL BrAC alcohol simulator solution. Conduct Test 1b three times. The vehicle must start.

Test 14. Radiofrequency Interference (RFI)/Electromagnetic Interference (EMI)

The Society of Automotive Engineers (SAE) Surface Vehicle Standard J1113 series, Required Function Performance Status, as defined in Surface Vehicle Standard J1113- 1

⁴ The amount of acetone specified is experimentally determined based on water to air partition factor of 365 to 1 at 34 °C to yield an acetone concentration in the air sample of 0.5 mg/liter.

for Class C devices (devices essential to the operation or control of the vehicle), and the International Special Committee on Radio Interference (CISPR), Subcommittee of International Electrotechnical Committee (IEC), specifically CISPR 25, will be used to evaluate BAIID electromagnetic immunity and compatibility. The test severity levels are specified below. The tests must be performed while the BAIID is in the drive and standby modes.

- a. J1113-1 2006-10 General and definitions. Electromagnetic Compatibility Measurement Procedures and Limits for Vehicles, Boats, and Machines (Except Aircraft) (16.6 Hz to 18 GHz).
- b. J1113-2 2004-07 Conducted immunity 30 Hz to 250 kHz- Power leads.

Level	Severity (volts, peak to peak)	Status
1	0.15	I
2	0.50	I
3	1.0	I
4	3.0	II

- c. J1113-4 2004-08 Conducted immunity - Bulk Current Injection (BCI) Method.

Level	Severity (milliamps)	Status
1	25 to 60	I
2	60 to 80	II
3	80 to 100	III
4	100	IV

d. J1113-11 2007-06 Immunity to Conducted Transients on Power Leads.

Pulse (12 v sys)	Level	Severity (volts)	Status
1	1	-25	I
	2	-50	II
	3	-75	II
	4	-100	IV
2a	1	25	I
	2	40	II
	3	50	II
	4	75	IV
2b	1	10	I
3a	1	-35	I
	2	-75	II
	3	-112	II
	4	-150	IV
3b	1	25	I
	2	50	II
	3	75	II
	4	100	IV
4	1	-4	I
	2	-5	II
	3	-6	II
	4	-7	IV
5	1	87	IV

e. J1113-13 2004-11 Part 13: Immunity to Electrostatic Discharge.

Contact discharge	
Severity	Status
0- 4 kV	I
4- 8 kV	II
8 kV	IV
Air discharge	
0- 4 kV	I
4- 15 kV	II
15 kV	IV

f. J1113-21 2005-10 Immunity to Electromagnetic Fields, 30 MHz to 18 GHz.

Severity (V/M)	Status
Up to 60	I
60- 80	II
80- 100	III
100- 150	IV

g. J1113-22 2003-11 Immunity to magnetic fields

Severity (uT)	Status
40	I
40- 50	II
50- 80	III
80	IV

h. IEC CISPR 25 Limits of Radio Disturbance.

Radiated Disturbance Limits (1 M test distance, 120 kHz bandwidth)			
	30- 75 MHz	75- 400 MHz	400- 1000 MHz
a	$62 - 25.13 \times \log(F/30)$	$52 + 15.13 \times \log(F/75)$	63
b	$52 - 25.13 \times \log(F/30)$	$42 + 15.13 \times \log(F/75)$	53

a: broadband, quasi-peak detector

b: narrowband, average detector

limit in dB (uV/M) at frequency F

Conducted Transient Emissions	
Pulse Polarity	Maximum Pulse Amplitude (12 volt system) (V)
Positive	75
Negative	-100

Limits for Broadband Conducted Disturbances										
MHz	0.15- 0.3		0.53- 2.0		5.9- 6.2		30- 54		68- 108	
	P	QP	P	QP	P	QP	P	QP	P	QP
a	93	80	79	66	65	52	65	52	49	36
b	80	67	76	63	62	49	62	49	56	43

a: power lines, limit in dB (uV)

P: peak detector

b: control lines, limit in dB (uA)

QP: quasi-peak detector

Limits for Narrowband Conducted Disturbances						
MHz	0.15- 0.3	0.53- 2.0	5.9- 6.2	30- 54	68- 87	76- 108
a	70	50	45	40	30	36
b	60	50	45	40	40	46

a: power lines, limit in dB (uV)

limits by peak detection

b: control lines, limit in dB (uA)

Test 15. Service Interval Display

Initialize the BAIID to begin the service interval period. After thirty (30) days, the BAIID must prominently indicate that it must be taken to a designated maintenance facility for maintenance and data downloads within 7 days or the vehicle will not start and the event will be logged. Over the course of the 7-day lockout countdown, the BAIID must prominently indicate that the BAIID is in need of service and the time remaining until ignition lockout. During this period, the vehicle may be started if other conditions for starting the vehicle are met. At the end of the 7-day lockout period, the BAIID must prominently indicate that the BAIID is in need of service and the vehicle

must not start. Other tests (except Tests 14 and 16) may be performed during this 37-day period.

Test 16. Data Integrity and Format

Complete all other tests before performing Test 16. Download the data from the interlock data logger and compare it to the data recorded for each test. Disconnect, then reconnect the power to the interlock data logger. Download the data again and compare it to the first data download. No lost or corrupted data is allowed. Check the data format (i.e., date and time of event) to verify conformance with the sample format in Appendix D.

APPENDIX A — QUALITY ASSURANCE PLAN TEMPLATE

[Manufacturer name]

Quality Assurance Plan for

[Interlock name AND Model number]

[date]

This Quality Assurance Plan (QAP) and the operating instructions for the [Interlock name] provide step-by-step instructions for checking the accuracy of the calibration of a BAIID and the maintenance of the BAIID. (As noted in the Model Specifications, BAIIDs must hold calibration for at least 37 days (30 days + 7 day lockout countdown) and must prominently display the service interval and provide for a 7 day lockout countdown.)

-
1. Provide step-by-step instructions for checking the calibration of the BAIID. These instructions must include:
 - Indication of the period of time that the BAIID can maintain calibration;
 - Recommended calibrating unit(s) (listed on NHTSA's Conforming Products List of Calibrating Units for Breath Alcohol Testers) and instructions for using the calibrating unit(s);
 - Breath alcohol concentration to be used in the calibration check(s): 0.02 g/dL BrAC;

- Agreement of the calibration check with the breath alcohol concentration of the calibrating unit: not greater than ± 0.005 BrAC
 - Description of how to verify the accuracy of the BAIID reading of BrAC (e.g., from an instrument read out, printout, interlock data logger, etc.);
 - Description of actions that must be taken if the BAIID fails the calibration check.
2. Provide instructions on downloading the data from the interlock data logger.
 3. Provide instructions on how to maintain the BAIID (i.e., what must be examined during maintenance; any functions that require less frequent checks). Such instructions must detail any corrective action to be taken if the BAIID fails to perform as well as any events that would require a BAIID to be taken out of service and returned to the manufacturer.
 4. Provide instructions on how to check for tampering.
 5. Other information regarding quality assurance unique to this instrument, if any:

Contact information for the BAIID manufacturer regarding calibration and maintenance issues:

**APPENDIX B — SAMPLE FORMAT FOR DOWNLOADED DATA FROM THE
INTERLOCK DATA LOGGER**

Example 1. Acceptable start and drive cycle.

<u>Date</u>	<u>Time</u>	<u>Start Attempts (engine activity)</u>
4/21/07	0951	start attempt
		sample accepted
		BrAC (alcohol absent, e.g., 0.000, 0.008)
		starter active
	0952	engine on
	0956	retest
		sample accepted
		BrAC (alcohol absent, e.g., 0.000, 0.008)
	1032	engine off

Example 2. Acceptable start but fail rolling re-start:

<u>Date</u>	<u>Time</u>	<u>Start Attempts (engine activity)</u>
4/22/07	2316	start attempt
		sample accepted
		BrAC (alcohol absent, e.g., 0.008)
		starter active
	2317	engine on
	2319	retest
		BrAC (alcohol present, e.g., 0.025)
		warning given

4/23/07 0047 engine off

Example 3. Push start:

Date Time Start Attempts (engine activity)

4/23/07 2054 ignition keyed

warning given

starter not active

2055 engine on

warning given

2120 engine off

Example 4. Start attempted but alcohol detected. Retry.

Date Time Start Attempts (engine activity)

4/21/07 1652 start attempt

sample accepted

BrAC (alcohol present, e.g., 0.030)

1653 warning given

1656 start attempt

sample accepted

BrAC (alcohol absent, e.g., 0.015)

starter active

1657 engine on

1702 retest

sample accepted

BrAC (alcohol absent, e.g., 0.010)

1850 engine off

Example 5. Start attempted using filtered sample. Retry.

<u>Date</u>	<u>Time</u>	<u>Start Attempts (engine activity)</u>
4/15/07	2016	start attempt
		low temp
		warning given
	2205	start attempt
		sample accepted
		BrAC (alcohol absent, 0.000)
		starter active
	2206	engine on
	2352	engine off

Example 6. Calibration Check.

<u>Date</u>	<u>Time</u>	<u>Start Attempts (engine activity)</u>
4/28/07	0900	start attempt
		sample accepted
		BrAC (alcohol absent, 0.000 or 0.008)
		starter active
	0903	engine on
	0926	retest
		sample accepted
		BrAC (alcohol absent, 0.000 or 0.008)
	1032	engine on

1045 Calibration check

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Issued on: **May 3, 2013**

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National Highway Traffic Safety Administration

Billing code 4910-59-P

[FR Doc. 2013-10940 Filed 05/07/2013 at 8:45 am; Publication Date: 05/08/2013]